

**REMARKS/ARGUMENTS*****Status of Claims***

Claims 7-17 have been canceled.

Claims 18-22 have been withdrawn.

Claims 1-6 are currently pending in this application.

Applicants hereby request further examination and reconsideration of the presently claimed application.

***Examiner Interview***

Applicants thank the Examiner for extending the courtesy of a telephonic interview on April 23, 2009 wherein the pending claims and the prior art of record were discussed. The Interview Summary mailed on April 27, 2009 accurately reflects the content of the interview.

***Claim Rejections – 35 U.S.C. § 102 and 35 U.S.C. § 103***

Claims 1 and 2 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Robertson, et al., U.S. Patent No. 4,956,388 (hereinafter “*Robertson*”). Claims 1-6 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Robertson*, in view of Wheeler et al. Journal of Labelled Compounds and Radiopharmaceuticals, 1996, Vol. 36, 3, pp.213-223 (hereinafter *Wheeler*).

The pending claims depend from independent claims 1 and 5, thus the pending claims stand or fall on the application of the cited references to independent claims 1 and 5. According to MPEP § 2131, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” Likewise, the United States Supreme Court in *Graham v. John Deere Co.*

of *Kansas City* noted that an obviousness determination begins with a finding that “the prior art as a whole in one form or another contains all” of the elements of the claimed invention. See *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 22 (U.S. 1966). Applicants respectfully submit that for the following reasons the cited references either singly or in combination fail to teach or contain all of the elements of the claims 1 and 5 and thus, cannot anticipate or render obvious the pending claims.

Applicants’ claim 1 recites:

A process for preparing (+)duloxetine, or an acid addition salt thereof, which process comprises:

- (i) resolving racemic ( $\pm$ )duloxetine with a chiral acid so as to obtain a salt of the chiral acid and (+)duloxetine, substantially free of (-)duloxetine; and
- (ii) if desired, converting the salt prepared in step (i) to the free base or a further acid addition salt.

See *supra*, emphasis added. Applicants have claimed *a salt of the chiral acid and (+)duloxetine substantially free of (-)duloxetine*. Similar limitations are recited in claim 5 of the instant application. The Office Action has asserted “[t]he term “substantially free of (-) duloxetine” does not carry patentable weight because the limiting steps and the resulting product from the prior art is (+) duloxetine as Example 14 showing active optical rotation as  $[\alpha]_{589} = +82^\circ \dots$ . There is no reason to believe that prior art compound is not optically pure.” See Office Action 2-3.

Applicants respectfully submit the disclosure of a positive value of optical rotation for the compositions disclosed by *Robertson* does not provide evidence the compositions are *substantially free of (-)duloxetine* as instantly claimed. One of ordinary skill in the art would surmise based on the positive value of the optical rotation that the compositions of *Robertson* possess an enantiomeric excess of the (+) isomer.

Further, as shown in Exhibit A of the attached Inventor Declaration, Applicants have prepared enantiomerically pure (+) duloxetine maleate in accordance with the experimental data provided and find by chiral HPLC the composition to be substantially free of the (-) isomer and to have a  $[\alpha]_{589} = +98^\circ$  at C=1 in methanol. The (+) duloxetine maleate composition disclosed by *Robertson* in Example 14 has an  $[\alpha]_{589} = +82^\circ$  at C=1 in methanol. On the basis of this value, Applicants calculated the optical purity ( $O_p$ ) of the *Robertson* composition as follows:  $O_p = [+82^\circ]_{\text{observed}} / [+98^\circ]_{\text{max}} \times 100\% = 84\%$ . The compositions of *Robertson* are calculated to have an optical purity of 84% with respect to the (+) isomer. Thus, the compositions of *Robertson* **are not substantially free of (-) duloxetine**.

Applicants respectfully submit *Robertson* does not teach each and every element of the instantly claimed subject matter and the secondary references do not remedy these deficiencies. Thus, the pending claims are neither anticipated by nor obvious in view of the cited references. Applicants respectfully request withdrawal of the rejections and allowance of the pending claims.

**CONCLUSION**

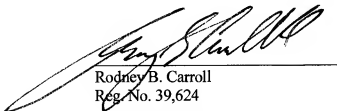
Consideration of the foregoing amendments and remarks, reconsideration of the application, and withdrawal of the rejections are respectfully requested by Applicants. No new matter is introduced by way of the amendment. It is believed that each ground of rejection raised in the Final Office Action dated November 18, 2008 has been fully addressed. If any fee is due as a result of the filing of this paper, please appropriately charge such fee to Deposit Account Number 50-1515 of Conley Rose, P.C., Texas. If a petition for extension of time is necessary in order for this paper to be deemed timely filed, please consider this a petition therefore.

If a telephone conference would facilitate the resolution of any issue or expedite the prosecution of the application, the Examiner is invited to telephone the undersigned at the telephone number given below.

Respectfully submitted,  
CONLEY ROSE, P.C.

Date: \_\_\_\_\_

5.18.09

  
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